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| 10/517,989   | 01/25/2005  | Lars Wik             | 55320.001091        | 7254             |
| 21967 7590 07/21/2010<br>HUNTON & WILLIAMS LLP<br>INTELLECTUAL PROPERTY DEPARTMENT<br>1900 K STREET, N.W.<br>SUITE 1200<br>WASHINGTON, DC 20006-1109 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| JANG, CHRISTIAN YONGKYUN   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/517,989

**Applicant(s)**

WIK, LARS

**Examiner**

CHRISTIAN JANG

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 30-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,7,8,11-14 and 18-29 is/are rejected.
- 7) ☒ Claim(s) 1-3,5,6,9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 11/23/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed on April 6<sup>th</sup>, 2010. Claims 1-14 and 18-35 are pending in the instant application. Claims 18-35 have been newly added.

### ***Election/Restrictions***

2. Newly submitted claims 30-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- a. Group 1, claim(s) 1-14 and 18-29, drawn to a device for detecting placement of an intubation/endo-tracheal tube.
  - b. Group 2, claim(s) 30-35, drawn to a method of monitoring placement of an endo-tracheal tube.
4. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined, as per 37 CFR 1.475, as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. In light of the rejection for claim 4 below, contain the same technical features as claims 30 and 33, the method claims do not have any special technical features which would satisfy Unity of invention. As such, the technical features found in claims 30 and 33 are not special technical features as it does not make a contribution over the prior art in review of Zacouto (USP #5,305,745). Further, they constitute separate inventions as being drawn to a process (Group 2) and an apparatus for its practice (Group 1).

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Objections***

6. Claim 1 is objected to because of the following informalities: In lines 1 and 2 - "An apparatus for capable of" should be amended to "An apparatus capable of"; in line 3 - "endo tracheal tubefor" should be "endo-tracheal tube for"; "in-the" in line 13 should be "in the". Appropriate correction is required.

7. Claim 5 is objected to because of the following informalities: "and to -identify" in line 2 should be "and to identify". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 18-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claim 18 recites the limitation "the indication of placement" in line 7. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 4, 7, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Zacouto (USP #5,305,745).
13. As to claim 4, Zacouto teaches an apparatus and corresponding method comprising a processing unit for identifying changes upon ventilation (col. 4 lines 16-19; microprocessor 19'), a measuring unit comprising at least two measuring electrodes for measuring thoracic impedance of a body (measuring impedance circuit 21'), the

measuring unit being in communication with the processing unit (Fig. 9), a power source for the apparatus (battery 7'), a display or alarm device (22') wherein the processing unit is programmed to identify impedance changes above a specific threshold value (col. 36 lines 18-32). It is noted that Zacouto does not teach that the device is programmed to indicate the placement of an endo-tracheal tube for ventilation as recited in the preamble of the claim. However, the preamble, in this case, merely states the purpose or intended use of the invention, rather than any distinct definition of any of the claimed inventor's limitations, and as such is not considered a limitation and is of no significance to claim construction (see MPEP 2111.02).

14. As to claim 7, Zacouto teaches storage means (col. 31 lines 64-67).
15. As to claim 11, Zacouto teaches an audiovisual alarm device (22').
16. As to claim 12, Zacouto teaches a user interface for inputting reference values (col. 36 lines 18-32 - adjustable threshold value for each subject implies there is inherently some sort of user interface for inputting values).
17. As to claim 13, Zacouto teaches integration in a defibrillating device (col. 3 lines 14-17).
18. As to claim 14, Zacouto teaches an endo-tracheal tube for ventilation (col. 3 lines 26-28).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zacouto (USP #5,305,745).
21. As to claim 8, Zacouto fails to teach an on/off switch which would give a start/stop signal. However, the use of a switch to prevent unnecessary use of power is a well known and widely utilized concept in any field of endeavor involving devices powered electrically. As such, it would have been obvious to one of ordinary skill in the art to incorporate an on/off switch to conserve power when measurements are not being made.

***Allowable Subject Matter***

22. Claims 1-3 are allowed.
23. Claims 5, 6, 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
24. Claims 18-29 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
25. The following is a statement of reasons for the indication of allowable subject matter:
- c. As to claim 1, the prior art of record fails to teach or fairly suggest the indication of a correct placement of an endo-tracheal tube by detecting a change in the impedance amplitude.

- d. As to claim 5, the prior art of record fails to teach the indication of incorrect intubation of an endo-tracheal tube in a recipient by identifying if the impedance value is equal to or greater than the specific value.
- e. As to claim 6, the prior art of record fails to teach the indication of incorrect intubation by identifying if the impedance value is greater than the specified threshold.
- f. As to claim 9, the prior art of record fails to teach the processing unit programmed to identify impedance changes above 0.5 ohms.
- g. As to claim 10, the prior art of record fails to teach the repeating of operations over a period of time to monitor the placement of the endo-tracheal tube for ventilation.
- h. As to claim 18, the prior art of record fails to teach the indication of placement of an intubation tube as a change in said measured thoracic impedance as compared to said specific threshold value.

***Response to Arguments***

- 26. Applicant's arguments, with respect to claim 1 has been fully considered and are persuasive. The rejections of claim 1 has been withdrawn.
- 27. Applicant's arguments with respect to claim 4 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Thurs (10-9:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. J./  
Examiner, Art Unit 3735  
7/8/10

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735